



# BEST AVAILABLE COPY

1637  
JFW

PATENT

Customer No. 22,852  
Attorney Docket No. 3495.0010-20

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
Marc ALIZON et al. ) Group Art Unit: 1637  
Application No.: 08/308,219 ) Examiner: Jeffrey N. FREDMAN  
Filed: September 19, 1994 ) Confirmation No.: 4832  
)

For: DNA SEQUENCE OF THE LTR REGION OF HUMAN  
IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) (as amended)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

### TRANSMITTAL LETTER

Applicants enclose the following papers. Kindly associate them with the above-identified application.

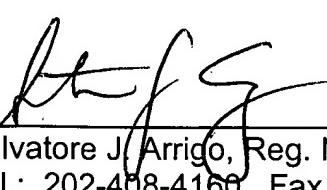
1. Petition to Suspend Action under 37 C.F.R. § 1.103 (4 pages with Exhs. 1-5).
2. \$200 Check for fee required by 1.17(g).

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: November 28, 2005

By:   
Salvatore J. Arrigo, Reg. No. 46,063  
Tel.: 202-408-4160 Fax.: 202-408-4400  
E-mail: arrigos@finnegan.com



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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**PETITION TO SUSPEND ACTION UNDER 37 C.F.R. § 1.103**

Applicants respectfully request suspension of action in this application under 37 C.F.R. § 1.103 for a period of six months. This suspension is necessary to allow applicants time to determine the correct assignee(s) of the application so that a Terminal Disclaimer signed by the correct assignee(s) can be filed to overcome an outstanding rejection under the judicially created doctrine of obviousness-type double patenting in this application. Applicants' petition should be granted in view of the following facts:

1. In an Office Action dated April 25, 2005, the office rejected claims 1-6, 29, and 32 in this application under the judicially created doctrine of obviousness-type double patenting over claims 1-6 of U.S. Patent No. 6,627,395. (Exhibit 1 at 6.)
2. Applicants filed a Reply on October 25, 2005. (Exhibit 2.)

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3. Thus, in compliance with 37 C.F.R. § 1.103(a), no reply to an Office Action is currently required.
4. The \$200.00 fee required by 1.17(g) is enclosed.
5. In the Reply filed October 25, 2005, applicants agreed to file a Terminal Disclaimer once applicants have determined the correct inventors and ownership of this application. (Exhibit 2 at 3.)
6. The instant application is a division of application Serial No. 07/158,652, filed February 22, 1998 (pending), which is a division of application Serial No. 06/771,248, filed August 30, 1985 (now abandoned). This application is also a continuation-in-part of application Serial No. 07/999,410, filed December 31, 1992 (pending), which is a continuation of application Serial No. 07/499,210 filed March 19, 1990 (pending), which is a continuation of application Serial No. 06/771,230, filed August 30, 1985 (now abandoned), which is a continuation-in-part of application Serial No. 06/706,562, filed February 28, 1985 (now abandoned), which is a continuation-in-part of application Serial No. 06/558,109, filed December 5, 1983 (now abandoned). (Exhibit 3 at 2.)
7. U.S. Patent No. 6,627,395 is a continuation of application Ser. No. 08/019,297, filed Feb. 18, 1993, which is a division of application Ser. No. 07/876,297, filed Apr. 30, 1992, now abandoned, which is a continuation application of Ser. No. 07/117,937, filed Nov. 5, 1987, now U.S. Pat. No. 5,135,864, which is a continuation application of Ser. No. 06/785,638, filed Oct. 8, 1985, now U.S. Pat. No. 4,708,818, which is a continuation application of Ser. No. 06/558,109, filed Dec. 5, 1983, now abandoned. (Exhibit 4 at face page.)

8. U.S. Patent No. 6,627,395 is currently assigned to Institut Pasteur and The United States of America as represented by the Secretary of the Department of Health and Human Services. (Exhibit 4 at face page.)
9. In contrast, the instant application is currently assigned to Institut Pasteur and Centre National de la Recherche Scientifique. (Exhibit 5.)
10. In order to file a Terminal Disclaimer in the instant application, the instant application and U.S. Patent No. 6,627,395 must be commonly owned. (See 37 C.F.R. § 1.321.)
11. Filing a Terminal Disclaimer will fix the expiration date of a patent issuing from the instant application as the same expiration date of U.S. Patent No. 6,627,395.
12. Thus, a suspension of action will not extend the term of a patent issuing from the instant application.

In view of the above facts, Institut Pasteur must determine the correct assignees of the claims of the instant application and the claims of U.S. Patent No. 6,627,395 and have the appropriate legal documents executed in order to file the required Terminal Disclaimer in the instant application. The difficulty in making this determination is complicated by the fact that the earliest claimed U.S. priority date in both applications is over 20 years ago. Nonetheless, Institut Pasteur is diligently trying to resolve this issue with the other assignees. Applicants believe that the above facts establish good and sufficient cause for a suspension of action in this application under 37 C.F.R. § 1.103 to allow time for Institut Pasteur to determine the correct assignees. Accordingly, applicants respectfully request a suspension of action for a period of six months in this application.

Please grant any extensions of time required to enter this response and charge  
any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: November 28, 2005

By: \_\_\_\_\_

  
\_\_\_\_\_  
Salvatore J. Arrigo  
Registration No. 46,063  
Telephone: 202-408-4160  
Facsimile: 202-408-4400  
E-mail: arrigos@finnegan.com



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
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P.O. Box 1450  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/308,219	09/19/1994	MARC ALIZON	3495.001020	4832
22852	7590	04/25/2005		EXAMINER
		FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413		FREDMAN, JEFFREY NORMAN
			ART UNIT	PAPER NUMBER
			1637	

RECEIVED

DATE MAILED: 04/25/2005

APR 27 2005

FINNEGAN, HENDERSON, FARABOW,  
GARRETT AND DUNNER, LLP

Please find below and/or attached an Office communication concerning this application or proceeding.

Docketed 4/27/05 Attorney Kim SIA  
Case 3495.001020  
Due Date 04/25/2005  
Action Response  
By SP

*Spars*

<b>Office Action Summary</b>	Application No.	Applicant(s)
	08/308,219	ALIZON ET AL.
Examiner	Art Unit	
Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 March 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 17-22,25 and 27-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 17-22 is/are allowed.
- 6) Claim(s) 25,29,32 and 35-40 is/are rejected.
- 7) Claim(s) 27,28,30,31,33 and 34 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/9/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.129(a)***

1. This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee under 37 CFR 1.17(r), the finality of the previous Office action is withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
3. Claims 25, 29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

Claims 25, 29 and 32 encompass a genus of nucleic acids which are different from those disclosed in the specification due to the use of the hybridizing language. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly described sequences as shown in the figures of the specification. Thus, applicant has express possession of only one particular HIV-1 genomic sequence, that given in claim 17, in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed which would be conserved among the different members of the genus. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

In the current situation, the definition of the HIV-1 sequences in claims 25, 29 and 32 lack any specific structure. This is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the specific sequence of claim 17, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to any sequence of HIV-1.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely but its functional utility, as an HIV-1 sequence without any definition of the particular changes permitted by the "HIV-1" language.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which "hybridizes to the DNA of claim 17". Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

***Claim Rejections - 35 USC § 112 – New Matter***

4. Claims 35-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes " If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

Here, the new limitation of the sequence "CTCAATAAGCTTGCCTTG" in claims 35-40 is apparently new matter. The response does not point out any support for the new limitation to this specific sequence in the specification. A careful review by the examiner of the specification and drawings failed to identify any support for this new limitation.

Since no basis has been found to support the new claim limitation in the specification, the claim is rejected as incorporating new matter.

***Double Patenting***

5. Claims 25, 29 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,627,395. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims represent a species which anticipates the current generic claims.

Claims 1-6 of U.S. Patent No. 6,627,395 teach a method for preparing and detecting HIV-1 RNA from a lysate of an HIV-1 virus, said method comprising: (a) providing a biological sample that comprises human CD4+ lymphocytes infected with HIV-1 virus; (b) separating said virus from said human CD4+ lymphocytes; (c) centrifuging said separated virus to form a fraction comprising concentrated virus; (d) isolating said fraction comprising concentrated virus; (e) lysing said virus; (f) precipitating the RNA of said virus; and (g) detecting said viral RNA.

2. The method of claim 1, wherein said method comprises banding said virus on a sucrose gradient or a metrizamide gradient.

Art Unit: 1637

3. The method of claim 1, wherein said method comprises pelleting said virus.
4. The method of claim 3, wherein said method comprises precipitating said virus with polyethylene glycol.
5. The method of claim 1, wherein the virus is lysed with SDS.
6. The method of claim 1, wherein said nucleic acid is precipitated with trichloroacetic acid.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

#### ***Allowable Subject Matter***

7. Claims 17-22 are allowed.
8. Claims 27, 28, 30, 31, 33 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
9. The following is a statement of reasons for the indication of allowable subject matter: These sequences are novel and unobvious because the Chang patent expressly excludes a region of the sequence now claimed. The SstI fragment is absent

from Chang and from Chang's clone, rendering Chang unable to anticipate or make obvious claims which encompass this SstI fragment region. Applicant correctly contends that these claims encompass that region and are therefore unobvious over Chang. Therefore, these claims are novel and unobvious.

***Response to Arguments***

10. Applicant's arguments filed March 9, 2005 have been fully considered but they are not persuasive.

Applicant comments that there is no new matter. As noted above, the new matter rejection is written since no basis was identified and since no specific support for claims 35-40 was found in the specification or drawings.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

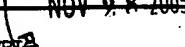
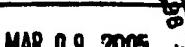
Application/Control Number: 08/308,219  
Art Unit: 1637

Page 9

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

4/26/05

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>																	
<b>Complete if Known</b>																	
Sheet	1	of	1														
																	
																	
<p>IDS Form PTO/SB/08: Substitute for form 1449A/PTO-8  <b>NOV 9 2003</b></p>																	
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>08/308,219</td> </tr> <tr> <td>Filing Date</td> <td>September 19, 1994</td> </tr> <tr> <td>First Named Inventor</td> <td>Marc ALIZON et al.</td> </tr> <tr> <td>Art Unit</td> <td>1637</td> </tr> <tr> <td>Examiner Name</td> <td>Jeffrey N. FREDMAN</td> </tr> <tr> <td colspan="2">Attorney Docket Number</td> </tr> <tr> <td colspan="2">3495.0010-20</td> </tr> </table>				Application Number	08/308,219	Filing Date	September 19, 1994	First Named Inventor	Marc ALIZON et al.	Art Unit	1637	Examiner Name	Jeffrey N. FREDMAN	Attorney Docket Number		3495.0010-20	
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3495.0010-20																	
<b>MAR 09 2005</b>																	

## **U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS**

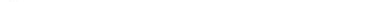
**Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004**

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials <sup>1</sup>	Cite No. <sup>2</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

## **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>6</sup>

Examiner Signature  Date Considered 4/20/05

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



PATENT  
Customer No. 22,852  
Attorney Docket No. 3495.0010-20

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Marc ALIZON et al.

Application No.: 08/308,219

Filed: September 19, 1994

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Group Art Unit: 1637  
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Examiner: Jeffrey Norman Fredman  
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Confirmation No.: 4832  
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For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY  
VIRUS TYPE 1 (HIV-1) (as amended)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**RESPONSE**

In response to the Office Action dated April 25, 2005, the period for response to which has been extended by filing a Petition for Extension of Time and fee concurrently herewith, applicants submit the following remarks.

REMARKS

Reconsideration of this application is respectfully requested.

Claims 17-22, 25, and 27-40 are pending in this application with claims 17-22 allowed.

Claims 25, 29, and 32 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had possession of the claimed invention at the time the application was filed. The Office bases the rejection on an alleged lack of written description of sequences that hybridize to the DNA of claim 17.

Applicants traverse the rejection. Claims 25, 29, and 32 are directed to *generic methods* for preparing and detecting the presence of HIV-1 RNA. These methods do not require knowledge of the sequence of the HIV-1 virus that is prepared and detected. Thus, applicants need not provide the sequence of all HIV-1 viruses to describe a generic method that will work with all of these viruses. Moreover, the Office has set forth no reasons to doubt that the claimed methods will work regardless of the sequence of the HIV-1 virus that is prepared and detected. Accordingly, applicants respectfully request withdrawal of the rejection.

Furthermore, the Office alleged that: "[c]laims 25, 29, and 32 encompass a genus of nucleic acids which are different from those disclosed in the specification *due to the use of hybridization language.*" (Office Action at 3, emphasis added.) The Office has overlooked that claims 29 and 32 do not contain "*hybridization language.*" Thus, the

basis for the Office's rejection of claims 29 and 32 is in error, and applicants respectfully request withdrawal of the rejection.

Claims 35-40 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had possession of the claimed invention at the time the application was filed. The Office contends that the specification does not support the limitation "CTCAATAAGCTTGCCTTG."

Applicants traverse the rejection. The limitation "CTCAATAAGCTTGCCTTG" can be found on page 13, line 13, of the specification. Thus, the basis for the Office's rejection of claims 35-40 is in error, and applicants respectfully request withdrawal of the rejection.

Claims 25, 29, and 32 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-6 of U.S. Patent No. 6,627,395. Solely to expedite prosecution of this application and not in acquiescence to this rejection, applicants agree to file a Terminal Disclaimer once applicants have determined the correct inventors and ownership of this application.

Claims 27, 28, 30, 31, 33, and 34 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. Applicants traverse the objection. As discussed above, the "base" claims 25, 29, and 32 are allowable. Accordingly, this objection is moot.

Applicants respectfully submit that this application is in condition for allowance. In the event that the Examiner disagrees, he is invited to call the undersigned to discuss any outstanding issues remaining in this application in order to expedite prosecution.

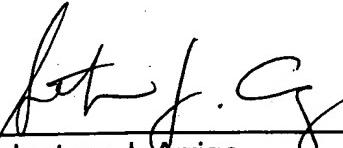
Please grant any extensions of time required to enter this response and charge  
any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: October 25, 2005

By:

  
\_\_\_\_\_  
Salvatore J. Arrigo  
Registration No. 46,063  
Telephone: 202-408-4160  
Facsimile: 202-408-4400  
E-mail: arrigos@finnegan.com



PATENT  
Customer No. 22,852  
Attorney Docket No. 3495.0010-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
Marc ALIZON et al. ) Group Art Unit: 1634  
Application No.: 08/308,219 ) Examiner: Jeffrey Norman Fredman  
Filed: September 19, 1994 )  
For: DNA SEQUENCE OF THE LTR REGION OF HUMAN IMMUNODEFICIENCY  
VIRUS TYPE 1 (HIV-1) (as amended)

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

REQUEST FOR EXAMINATION AFTER FINAL UNDER 37 C.F.R. § 1.129(a)

Applicants hereby request the above-identified application be examined according to the procedures set forth in 37 C.F.R. § 1.129(a). This application meets the criteria set forth in 37 C.F.R. § 1.129(a) since it has an actual filing September 19, 1994, and an effective filing date of, at least, August 30, 1985, and it is accompanied by a fee of \$770.00 as required by § 1.17(r).

Applicants hereby request that the finality of the Office Action be withdrawn and that the Amendment and Response to Paper No. 24 filed August 1, 2003 (with 1 Exhibit), and following amendments and remarks be entered and considered by the Examiner. Please amend this application as follows.

Amendments to the Claims are reflected in the listing of claims in this paper.

Remarks begin on page 6 of this paper.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)

AMENDMENTS TO THE SPECIFICATION:

Please replace the first paragraph of the specification with the following amended paragraph:

This is a division of application Serial No. 07/158,652 filed February 22, 1988 (pending), which is a division of application serial no. 06/771,248, filed August 30, 1985 (now abandoned). This application is also a continuation-in-part of application Serial No. 07/999,410, filed December 31, 1992 (pending), which is a continuation of application Serial No. 07/499,210 filed March 19, 1990 (pending), which is a continuation of application Serial No. 06/771,230, filed August 30, 1985 (now abandoned), which is a continuation-in-part of application Serial No. 06/706,562, filed February 28, 1985 (now abandoned), which is a continuation-in-part of application Serial No. 06/558,109, filed December 5, 1983 (now abandoned).

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4400  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

Claims 1-16 (canceled).

17. (not entered) A purified recombinant DNA of human immunodeficiency virus type 1 (HIV-1), wherein the DNA comprises the sequence:

8570	8580	8590	8600	8610
GGGGGACTGG	AAGGGCTAAT	TCACTCCCAA	CGAAGACAAG	ATATCCTTGA
8620	8630	8640	8650	8660
TCTGTGGATC	TACCACACAC	AAGGCTACTT	CCCTGATTGG	CAGAACTACA
8670	8680	8690	8700	8710
CACCAGGGCC	AGGGGTCAGA	TATCCACTGA	CCTTGATG	GTGCTACAAAG
8720	8730	8740	8750	8760
CTAGTACCAAG	TTGAGCCAGA	TAAGGTAGAA	GAGGCCAATA	AAGGAGAGAA
8770	8780	8790	8800	8810
CACCAGCTTG	TTACACCCCTG	TGAGCCTGCA	TGGAATGGAT	GACCCTGAGA
8820	8830	8840	8850	8860
GAGAAGTGTGTT	AGAGTGGAGG	TTTGACAGCC	GCCTAGCAT	TCATCACGTG
8870	8880	8890	8900	8910
GCCCGAGAGC	TGCATCCGGA	GTACTTCAAG	AACTGCTGAC	ATCGAGCTTG
8920	8930	8940	8950	8960
CTACAAGGGGA	CTTTCCGCTG	GGGACTTTCC	AGGGAGGCCT	GGCCTGGGCG
8970	8980	8990	9000	9010
GAACCTGGGGA	GTGGCGAGCC	CTCAGATGCT	GCATATAAGC	AGCTGCTTTT
9020	9030	9040	9050	9060
TGCCTGTACT	GGGTCTCTCT	GGTTAGACCA	GATTTGAGCC	TGGGAGCTCT
9070	9080	9090	9097	10
CTGGCTAACT	AGGAAACCCA	CTGCTTAAGC	CTCAATA	AAGCTTGCCT
20	30	40	50	60
TGAGTGCTTC	AAGTAGTGTG	TGCCCGTCTG	TTGTGTGACT	CTGGTAACTA

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1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
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70	80	90	100	110
GAGATCCCTC	AGACCCTTT	AGTCAGTGTG	GAAAATCTCT	AGCAGTGGCG
120	130	140	150	159
CCCGAACAGG	GAATTGAAAG	CGAAAGGGAA	ACCAGAGGAG	CTCTCTCGA

18. (not entered) The purified recombinant DNA of claim 17, wherein said nucleic acid is labeled with a label selected from the group consisting of a radioisotope, an enzyme, a fluorescent label, and a chromophore label.

19. (new) A method of using the purified recombinant DNA of claim 17 for detecting the presence of HIV-1 RNA comprising:

- (a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;
- (b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA;

and

(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 17 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

20. (new) The method of claim 19, wherein the biological fluid is blood.

21. (new) A method of using the purified recombinant DNA of claim 18 for detecting the presence of HIV-1 RNA comprising:

- (a) providing a cell-free supernatant of a biological fluid comprising cells infected with HIV-1;
- (b) disrupting HIV-1 virions in the cell-free supernatant to release HIV-1 RNA;

and

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
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(c) detecting the presence of HIV-1 RNA by contacting the HIV-1 RNA with the purified recombinant DNA of claim 18 and detecting hybridization between the HIV-1 RNA and the purified recombinant DNA.

22. (new) The method of claim 21, wherein the biological fluid is blood.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)

REMARKS

Reconsideration of this application is respectfully requested.

Applicants have amended the specification to add a priority claim under 35 U.S.C § 120.

Claims 19-22 are new and are fully supported by the specification, for example, on page 14, lines 17-32. Upon amendment, claims 17-22 are pending in this application. No new matter enters by amendment.

Claim 15 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chang et al. (U.S. Patent No. 6,001,977), and claim 16 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chang et al. in view of White et al. (U.S. Patent No. 4,677,054). The Examiner contends that it would have been *prima facie* obvious to select applicants' sequence from Chang's sequence.

Applicants traverse the rejection. For the reasons presented in Applicants' August 1, 2003, Amendment, Chang cannot make applicants' claims 17-22 obvious. Accordingly, applicants respectfully request withdrawal of the rejection.

Applicants respectfully submit that this application is in condition for allowance. In the event that the Examiner disagrees, he is invited to call the undersigned to discuss any outstanding issues remaining in this application in order to expedite prosecution.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

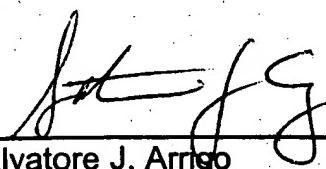
FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

By:

  
Salvatore J. Arrigo  
Registration No. 46,063  
Telephone: 202-408-4160  
Facsimile: 202-408-4400  
E-mail: arrigos@finnegan.com

Dated: December 19, 2003

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)

UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION

PATENT NO. : 6,627,395 B1  
DATED : September 30, 2003  
INVENTOR(S) : Luc Montagnier et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page.

Item [30], Foreign Application Priority Data, delete the second occurrence of "Sep. 15, 1983 (GB) . . . 84/24800".

Signed and Sealed this

Thirtieth Day of December, 2003



JAMES E. ROGAN  
*Director of the United States Patent and Trademark Office*

51481

PATENT OR DESIGN: SOLE OR JOINT

ASSIGNMENT

FOR UNFILED APPLICATION FOR UNITED STATES PATENT

(Sole or Joint Inventors)

I.I. NAME(S) AND  
I.I. OFFICE ADDRESS(S)  
& INVENTOR(S),  
including country

WHEREAS:

- ALIZON Marc, 71, rue du Cardinal Lemoine 75005 PARIS (France)
- SONIGO Pierre 23, rue Gutemberg 75015 PARIS (France)
- STEWART Cole  
4Bis Villa Denise 92320 CHATILLON (France)
- DANOS Oliver 1, Place Rollet 75015 PARIS (France)
- WAIN-HOBSON Simon 3, rue Jean de la Fontaine  
78180 MONTIGNY LES BRETONNEUX (France)

FILE OF  
VENTION

(hereinafter referred to as ASSIGNEE), have invented and own a certain invention entitled:

CLONED DNA SEQUENCES RELATED TO THE GENOMIC RNA OF  
LYMPHADENOPATHY-ASSOCIATED VIRUS(LAV) AND... RNA

for which application for Letters Patent of the United States has been executed on even date  
XXXXXX, August 30, 1985,

I.I. NAME AND  
ADDRESS (including  
country) OF  
SIGNEE

INSTITUT PASTEUR

25-28, rue du Dr. Roux

WHEREAS: 75724 PARIS CEDEX 15 (France) and  
CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE  
15, Quai Anatole France  
75007 PARIS (France)

(hereinafter referred to as ASSIGNEE), is desirous of acquiring the entire interest in, to and  
under said invention and the United States Letters Patent to be obtained therefor;

NOW, THEREFORE, TO ALL WHOM IT MAY CONCERN: Do it known that in consideration of  
the payment by ASSIGNEE to ASSIGNEE of the sum of One Dollar (\$1.00), the receipt of which  
is hereby acknowledged, and for other good and valuable consideration, ASSIGNEE hereby sells,  
assigns and transfers to ASSIGNEE the full and exclusive right, title and interest to said invention  
and all Letters Patent of the United States to be obtained therefor on said application or  
any continuation, division, renewal, substitute or revision thereof for the full term or terms for  
which the same may be granted.

ASSIGNEE hereby covenants that no assignment, sale, agreement or encumbrance has been  
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ASSIGNEE further covenants that ASSIGNEE will, upon its request, be provided promptly  
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Letters Patent as may be known and accessible to ASSIGNEE and will testify as to the same  
in any interference or litigation related thereto and will promptly execute and deliver to  
ASSIGNEE or its legal representatives any and all papers, instruments or affidavits required to  
apply for, obtain, maintain and enforce said application, said invention and said Letters  
Patent which may be necessary or desirable to carry out the purposes hereof.

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sign application.

IN WITNESS WHEREOF, I/We have hereunto set hand and seal this 7-2-1986

(Date of Signing)

NATURE(S)  
(or signature(s) must  
correspond with the  
name(s) of the  
individual(s) above.)

Stewart

Pierre SONIGO

Maub

→ Marc ALIZON

Simon Wain-Hobson

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